



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/333,703 06/16/99 TANG

P 243/245

HM22/0605
BETH A. BURROUS OR JOHN P. ISACSON
FOLEY & LARDNER
WASHINGTON HARBOUR
3000 K STREET, N.W. SUITE 500
WASHINGTON DC 20007-5109

EXAMINER

GHASHGHAEF, F

ART UNIT

PAPER NUMBER

1656

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/333,703	Applicant(s) TANG ET AL.	
	Examiner Fariba Ghashghaee	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Original claims were 1-15. Claims were restricted to three distinct groups in office action mailed on March 9, 2001 (paper No. 5). Applicant has elected group III which includes claims 8-15, drawn to an assay procedure, on April 9, 2001 (paper No. 13).

It is reminded that the examination is only considered based on the elected claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al. (WO 96/40116).

Claims 8-15 are drawn to a method of identifying one or more indolinone compounds that inhibit growth factor-stimulated cell proliferation, comprising :

(a) contacting cells with one or more indolinone compounds; (b) contacting said cells with one or more growth factors selected from VEGF, PDGF, and FGF; and

(c) monitoring an effect upon said cells. And a method of treating and preventing an abnormal condition by administering to a patient in need of such treatment a

Art Unit: 1656

pharmaceutically acceptable composition comprising a therapeutically effective amount of said compounds by the aforementioned method.

Tang et al. teaches a method of identifying one or more indolinone compounds that inhibit growth factor stimulated cell proliferation by using indolinone compounds and teaches that these compounds are capable of modulating, regulating and/or inhibiting tyrosine kinase signal transduction. Tang also teaches that such compounds are useful for the treatment of diseases such as cancer, atherosclerosis, arthritis, and restenosis and metabolic diseases such as diabetes (See page 5, lines 19-25). Furthermore, Tang teaches that their indolinone compounds (See pages 5-10), is further directed to pharmaceutical compositions comprising a pharmaceutically effective amount of the indolinone compounds and a pharmaceutically acceptable carrier or excipient. Tang adds that these compositions may be included in methods for treating diseases such as cancer, and other disorders related to abnormal vasculogenesis and/or angiogenesis (See page 10, lines 9-24), and routes of administration such as parental delivery (See page 24, lines 30-36). Also, Tang et al. teaches the effective dosage and explains that the effective dosage is when the active ingredients are contained in an amount effective to achieve its intended purpose

And determination of a therapeutically effective amount was well within the capability of those skilled in the art (See page 29, lines 28-38, and page 30, lines 30-37). In addition, Tang teaches the effect of these indolinone compounds on the growth factors selected from the group consisting of VEGF, PDGF, and FGF and monitors an effect upon said

Art Unit: 1656

cells (See pages 83-92). Tang explains the effect of his composition on human smooth muscle cells growth (See page 85, lines 14-24).

Claims 8-15 are rejected under 102(e) as being anticipated by Buzzetti et al. (US Pat. No. 5,840,745).

Buzzetti et al. discloses indolinone compounds and explains that these compounds possess specific tyrosine kinase inhibiting activity (See Abstract and columns 1-8). Buzzetti discloses that phosphorylation of the tyrosine kinase receptors plays an important role in signal transduction and the principal function of tyrosine kinase activity in normal cells is to regulate cell growth. Buzzetti adds that the indolinone compounds of his invention can be useful in the treatment of pathological proliferation disorders in mammals, including humans (See column 11, lines 33-50).

Buzzetti also teaches a method of administration of a therapeutically effective amount of the compounds of his inventions (See column 11, lines 51-67). In columns 11-14, Buzzetti explains the effective dosage and different methods of administering the compounds to a patient for both inhibition and treatment purposes(also see claims 5, 13).

Advisory Information

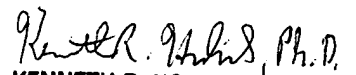
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fariba Ghashghaee whose telephone number is (703)305-3586. The examiner can normally be reached on 8:30 A.M.-4:30 P.M. on Mon.-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703)308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3014 for regular communications and (703)305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Fariba Ghashghaee
Examiner
Art Unit 1656


June 4, 2001


KENNETH R. HORLICK
PRIMARY EXAMINER 6/4/01
GROUP 1600